NOV 23 2011 K113280

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. GENERAL INFORMATION

Classification Name	Magnetic Resonance Diagnostic Device (21 CFR 892.1000)
Device Trade Name:	Carotid Coil GE1.5T
Applicant's Name and Address:	Tursiop Technologies, LLC 11000 Cedar Ave. Suite 280 Cleveland OH 44106
Submitter:	Raju Viswanathan Chief Technology Officer Tursiop Technologies, LLC 11000 Cedar Ave. Suite 280 Telephone: (216) 658-4521 Email: raju@tursiop.com

B. INTENDED USE

The Carotid Coil GE1.5T is a receive-only 2-channel diagnostic MR imaging coil designed for use at a static magnetic field strength of 1.5T with the GE Twinspeed HDx 1.5T MRI scanner/system. It is used for obtaining diagnostic images of the carotid arteries in the region of the neck and lower cranium.

C. DEVICE DESCRIPTION

The Carotid Coil GE1.5T is a receive-only 2-channel coil for operation at a magnetic field strength of 1.5T with the GE Twinspeed HDx system. The coil is a two-element coil consisting of two independent rectangular loops, each of approximate size 7 cm x 4.5 cm. Coupling of either coil element to the transmitted field is prevented through respective active blocking circuits.

The Carotid Coil GE1.5T is specially designed for MR imaging of the carotid arteries in the region of the neck and lower cranium. The coil provides optimum signal to noise ratio and coverage in the area of the carotid arteries, allowing high-resolution imaging, while the sensitive region of the coil covers an approximately 7 cm Field of View.

D. PERFORMANCE TESTING & STANDARDS

- IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995).
- IEC 60601-2-33 (2006): Medical electrical equipment-Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
- UL 94; Tests for Flammability of Plastic Materials for parts in Devices and Appliance
- ISO 10993-1 (2009): Biological evaluation of medical devices-Evaluation and testing within a risk management process
- NEMA: MS-6 (2008) Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images

- NEMA: MS-9 (2008) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA Standardized 510(k) Pre-Market Notification Submission Template for RF Coil Accessories Intended for Use with Magnetic Resonance Diagnostic Imaging Devices

E. PREDICATE DEVICES

The Carotid Coil GE1.5T is substantially equivalent to the predicate devices. The table below identifies similarities between the devices. Although the GE 3-inch General Purpose Coil is in commercial distribution it is not included in the FDA 510(k) database and/or has been purged from the FDA PMA database. Tursiop Technologies LLC has conducted side by side testing between the Carotid Coil GE1.5T and the GE 3-inch General Purpose Coil to verify substantial equivalence.

Parameter	Carotid Coil GE1.5T	TT1 General Purpose Coil (K083434)	Predicate Coil: GE 3-inch General Purpose Coil
Intended/Indications for Use	The Carotid Coil GE1.5T is a receive-only 2-channel diagnostic MR imaging coil designed for use at a static magnetic field strength of 1.5T with the GE Twinspeed HDx 1.5T MRI scanner/system. It is used for obtaining diagnostic images of the carotid arteries in the region of the neck and lower cranium.	The TT1 General Purpose Coil is a receive-only diagnostic MR imaging coil designed for use at a static magnetic field strength of 1.5T with the GE Signa® 1.5T system. It is used for obtaining diagnostic images of a variety of small-to-medium sized anatomical regions, such as jaw, spine, neck, shoulder, thigh, foot, ankle and joints.	The GE 3-inch General Purpose Coil is a receive-only RF coil designed for 1.5T MR imaging of various anatomical regions, such as jaw, spine, neck, shoulder, thigh, foot, ankle and joints.
Dimensions	Dimensions of each channel element: Coil length - 7 cm Coil width – 4.5 cm Similar in weight	Coil length - 7.5 cm Coil width - 7.5 cm Similar in weight	Coil length – 7.5 cm Coil width – 7.5 cm Similar in weight
Coil Architecture	Two channel receive-only for 1.5T operation	Single channel receive-only for 1.5T operation	Single channel receive-only for 1.5T operation
	Housing Type - Polycarbonate	Housing Type - ABS plastic	Housing Type - Fiberglass
	Primary Decoupling - Active/PIN diode-enabled blocking circuitry for each channel	Primary Decoupling - Active/PIN diode-enabled blocking circuitry	Primary Decoupling - Active/PIN diode-enabled blocking circuitry
Performance & Safety	IEC 60601-1, IEC60601-2-33 Flammability UL 94, ISO 10993-1,NEMA MS6, NEMA MS9	IEC 60601-1, IEC60601-2-33 Flammability UL 94, ISO 10993-1, NEMA MS6	IEC 60601-1, IEC60601-2-33 Flammability UL 94, ISO 10993-1, NEMA MS6

Principl. of Operation	Hydrogen nuclei excitation for imaging of the scanned organ	Hydrogen nuclei excitation for imaging of the scanned organ	Hydrogen nuclei excitation for imaging of the scanned organ
Technological Characteristics	Optimal Signal to Noise Ratio (SNR) and coverage allowing high-resolution imaging, while the sensitive region of the coil covers an approximately 7 cm Field of View.	Optimal Signal to Noise Ratio (SNR) and coverage allowing high-resolution imaging, while the sensitive region of the coil covers an approximately 10 cm Field of View.	Optimal Signal to Noise Ratio (SNR) and coverage and high resolution imaging

F. SAFETY AND EFFECTIVENESS

Tursiop Technologies, LLC complies with FDA's GMPs and is ISO 13485-certified for the design and manufacture of magnetic resonance imaging coils. The Carotid Coil GE1.5T complies with voluntary standards for safety/effectiveness (IEC 60601, UL 94, ISO 10993-1) all of which mandate that relevant components are tested to minimize hazards (electrical, mechanical, flammability, biocompatibility). The patient contacting surface is polycarbonate painted with biocompatible paint. ISO-mandated risk management practices have been utilized to assess potential risks throughout the device life cycle to mitigate unacceptable levels of risk by conducting risk assessment (FMEA) procedures.

Tursiop Technologies, LLC has conducted testing to establish the safety and effectiveness concerning the Carotid Coil GE1.5T. Side by side comparison testing was conducted with one of the predicate devices, GE 3-inch General Purpose Coil which demonstrated substantially equivalent performance. The Carotid Coil GE1.5T does not introduce any new potential safety risks and operates in a manner similar to the predicate devices.

G. SUBSTANTIAL EQUIVALENCE STATEMENT

The Carotid Coil GE1.5T is substantially equivalent to the GE 3-inch General Purpose Coil and the TT1 General Purpose Coil (K083434).

This opinion is based on the fact that comparing the Carotid Coil GE1.5T technological characteristics, coil architecture and operating principles with that of the predicate devices reveals that the devices comply with the same or equivalent standards and have the same or equivalent intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Tursiop Technologies LLC.
Mr. Mark Job
Responsible Third Party Official
% Regulatory Technology Services, LLC.
1394 25th Street NW
BUFFALO MN 55313

NOV 23 2011

Re: K113280
Trade/Device Name: Carotid Coil GE 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 4, 2011
Received: November 7, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113280

Device Name: Carotid Coil GE1.5T

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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